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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,402	ERIKA ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/15/04, 6/18/07+10/22/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-66* is/are pending in the application.

4a) Of the above claim(s) *17-20 and 32-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16 and 21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/04+10/04/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-10 are cancelled. Claims 11-66 are added. Claims 17-20 and 32-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/18/2007. Claims 11-16 and 21-31 are under examination.

Election/Restrictions

2. Applicant's election of Group I in the reply filed on 06/18/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Additionally, it is noted that Applicant's election with traverse of antacids species, in the reply filed on 06/18/2007 is acknowledged. The traversal is on the ground(s) that the species have unity with one another. This is not found persuasive. In order to have unity with one another, the species must share a special technical feature. And a special technical feature can be demonstrated if the species provide a contribution over the prior art. In the instant case, because the species do not provide a contribution over the prior art, the species do not share a special technical feature. Specifically, at the time the invention was filed, antacids are well known in the art. Thus, it does not provide a contribution over the prior art. In the absence of a contribution over the prior art, the technical feature shared among the species is not special. In the absence of a

shared special technical feature, the species lack unity with one another. See MPEP § 1850.

The requirement is still deemed proper and is therefore made FINAL.

4. The following is directed at Applicant's right to rejoinder: The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 11-16, 21-22 and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Vande-Velde.[1]

The claims are directed to a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance. Claim 12, which depends on claim 11, requires the gastric acid reducing substance to increase the pH in the stomach to between pH 4 and pH 7. Claims 13-14, which depend on claims 11-12, respectively, limit the gastric acid substance to those that inhibits or binds gastric acid, which is further limited to antacids by claims 15-16, respectively. Claims 21-22, which depend on claims 11-12, respectively, require antigenically active substance to be one or more natural antigens, synthetic antigens, antigen mimotopes or a combination thereof. Claims 30-31, which depend on claims 11-12, limit the antigenically active substance be a tumor antigen.

Vande-Velde teaches a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance. [Abstract, in particular.] The gastric acid reducing agent used by Vande-Velde is an antacid. The antigenically active substances that Vande-Velde teaches include natural and synthetic antigens and tumor antigens. [Claims, page 12, in particular.]

Vande-Velde teaches the claimed vaccine composition. Hence, Vande-Velde anticipates the claimed invention.

Regarding the limitation of claims 12, which requires the gastric acid reducing substance to increase the pH in the stomach to between pH 4 and pH 7, it should be noted that the vaccine composition of Vande-Velde does comprise at least one antacid. The purpose of antacid is to reduce stomach acid level. In view of the known properties of antacids, the vaccine composition of Vande-Velde would have inherently reduced stomach/gastric acid levels, when administered. Hence, while Vande-Velde may be silent on the pH level in the stomach of subjects receiving his vaccine composition, the composition of Vande-Velde does comprise an antacid. Therefore, his vaccine composition would necessarily increase the pH level in the stomach of subjects receiving the vaccine composition. Additionally, Vande-Velde et al. teaches the use of large volumes of antacids to neutralize stomach acids to avoid antigenic degeneration caused by stomach acid. [Paragraphs 002 and 0006, in particular.]

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[1] Vande-Velde, U.S. PreGrant Patent No. 20040013695.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Martin et al.[2]

Claim 23, which depends on claim 21, requires the natural or synthetic antigen be coupled to a carrier. Claims 24-25, which depend on claims 22-23, respectively, require the natural or synthetic antigen be conjugated to a carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. While Vande-Velde does suggest the addition of a carrier with his vaccine composition, it is not readily apparent if Vande-Velde coupled and/or conjugated the natural or synthetic antigen to the carrier. [Paragraph 0035, in particular.]

However, at the time the invention was made, Martin et al. establishes that the coupling and conjugation of antigen to a carrier stimulates the development of a stronger immune response. [Paragraph 0100, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to couple and conjugate antigens to a carrier. One of ordinary skill in the art, at

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[2] Martin et al. U.S. PreGrant Patent No: 20030049271, which has priority to U.S. Provisional No. 60/269841.

the time the invention was made, would have been motivated to do so to stimulate the development of a stronger immune response. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because coupling and conjugation are routinely practiced in the art.

9. Claims 23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Kricek et al.[3]

Claim 23 requires that the antigen mimotope be coupled to a carrier. Claims 26-27, which depend on claims 22-23, require the mimotope be conjugated to a carrier. Claims 28-29, which depend on claims 26-27, require that the mimotope be bounded to the carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. It is not readily apparent if Vande-Velde teaches mimotopes.

However, Kricek et al. teaches mimotopes and its conjugation to a carrier.

Hence, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Vande-Velde and Kricek et al. to yield a vaccine composition comprising an antigenic mimotope conjugated/bounded to a carrier and an antacid. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to avoid the antigenic degeneration of the composition of Kricek by stomach acid of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a

[3] Kricek et al. U.S. Patent No. 6610297.

reasonable expectation of success for doing so because the addition of antacid to vaccine compositions to avoid antigenic degeneration is routinely practiced in the art.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/4691622 in view of Vande-Velde.

Claims 11-16 are directed to a vaccine composition comprising an antigen and a gastric reducing substance.

Claim 14 of the copending application is directed to a composition comprising an antigen. The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the composition of claim 14. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection.

12. Claims 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 89 of copending Application No. 10/490920 in view of Vande-Velde.

Claim 89 is directed to a vaccine composition comprising an antigen. C The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the vaccine composition of claim 89. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/